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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/367,481	08/13/99	FUSHIKI T	35859.1

INTELLECTUAL PROPERTY GROUP
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HM22/1203

EXAMINER

COE, S

ART UNIT	PAPER NUMBER
1651	4

DATE MAILED: 12/03/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/367,481

Applicant(s)

Fushiki et al.

Examiner

Susan Coe

Group Art Unit

1651



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 9-23 is/are pending in the application

Of the above, claim(s) _____ is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 9-23 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☒ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

1. The preliminary amendment filed August 13, 1999 has been received and entered.
2. Claims 9-23 are currently pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Objections

3. Claim 23 objected to under 37 CFR 1.75(c) as being in improper form because a multiply dependent claims cannot depend on another multiply dependent claim. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 9-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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5. Claims 9, 10, 17, and 18 are rendered indefinite by the term “enhancing.” “Enhancing” is a relative term which renders the claim indefinite. The term “enhancing” is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. There are no definite means for determining the degree of improvement in the endurance of the subject.
6. Claim 20 is rendered indefinite because it depends on canceled claim 8. For the purposes of examination, claim 20 was assumed to depend on claim 18.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 17-20 and 22-23 are rejected under 35 U.S.C. 102(b) as being anticipated by US 3,764,692.

The claims are drawn to a composition comprising a food and (-) hydroxycitric acid, or a lactone or a water-soluble salt thereof. The hydroxycitric acid and its derivatives are extracted from garcinia pericarps.

US '692 is drawn to an orally administered composition for treating obesity. The active ingredient of the composition is (-) hydroxycitric acid derived from the fruit of *G. cambogia*.

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The (-) hydroxycitric acid can also be used in lactone form or as a pharmaceutically acceptable salt such as the sodium or potassium salt of the acid (column 1, lines 27-46; column 2, lines 1-5; and claims 1 and 7).

The hydroxycitric acid free acid, salt, and lactone can be administered with any pharmaceutically acceptable carrier such as water, gelatin, starch, or vegetable oil (see column 2, lines 26-35). All of these carriers are considered food. Even though the reference does not specifically disclose administering the compounds in the specific foods claimed in claim 23, it is still considered to anticipate this claim because any type of food is a pharmaceutically acceptable carrier for an orally administered composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 3,764,692 in view of US Pat. No. 5,536,516.

The claims are drawn to a composition comprising a food and (-) hydroxycitric acid, or a lactone or a water-soluble salt thereof. The hydroxycitric acid and its derivatives are extracted from garcinia pericarps. The garcinia is *Garcinia cambogia*, *Garcinia indica*, or *Garcinia atroviridis*.

US '692 is drawn to an orally administered composition for treating obesity. The active ingredient of the composition is (-) hydroxycitric acid extracted from *G. cambogia*. The (-) hydroxycitric acid can also be used in lactone form or modified into a pharmaceutically acceptable salt such as the sodium or potassium salt of the acid (column 1, lines 27-46; column 2, lines 1-5; and claims 1 and 7). The hydroxycitric acid free acid, salt, and lactone can be administered with any pharmaceutically acceptable carrier such as water, gelatin, starch, or vegetable oil (see column 2, lines 26-35). All of these carriers are considered food. Even though the reference does not specifically disclose administering the compounds in the specific foods claimed in claim 23, it is still considered to anticipate this claim because any type of food is a pharmaceutically acceptable carrier for an orally administered composition. While this reference teaches orally administering the claimed (-) hydroxycitric acid and derivatives, it does not teach extracting the (-) hydroxycitric acid from *G. indica* or *G. atroviridis*.

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US '516 teaches that free acid and lactone forms of hydroxycitric acid can also be extracted from the fruit of *G. indica* and *G. atroviridis* and *G. cambogia* (see column 1, lines 7-10). These compounds are used for oral administration. This disclosure shows that the presence of orally administrable hydroxycitric acid in extracts from *G. indica* and *G. atroviridis* was known in the art at the time of the invention. Based on the disclosure by US '516 that hydroxycitric acid can be extracted from *G. indica* and *G. atroviridis* as well as the *G. cambogia* disclosed by US '692, a person of ordinary skill in the art would have had a reasonable expectation that hydroxycitric acid could be successfully extracted from *G. indica* and *G. atroviridis*. Therefore, the artisan of ordinary skill would have been motivated to use *G. indica* and *G. atroviridis* as a source of hydroxycitric acid based on the disclosure by US '516.

9. Claims 9-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over US '692 in view of US '516 and McCarty (Medical Hypotheses (1995) Vol. 45, pages 247-254).

The claims are drawn to a method for increasing endurance during exercise by administering (-) hydroxycitric acid or a lactone or a water-soluble salt thereof.

As stated above, the composition claimed in 17-23 are considered anticipated and/or obvious over US '692 and US '516. These references teach the claimed hydroxycitric acid compositions, but they do not teach administering the compositions for increasing endurance during exercise. McCarty discloses that hydroxycitric acid compositions from garcinia used for inducing weight loss may also be used to increase endurance (see page 250). The hydroxycitric acid compositions of US '692 and US '516 are both used for reducing body weight. McCarty's

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disclosure shows that hydroxycitric acid compositions administered for weight loss can also be used to increase endurance during exercise. Based on McCarty's disclosure, a person of ordinary skill in the art would have had a reasonable expectation that the hydroxycitric acid compositions taught in US '692 and US '516 would have been useful in increasing endurance. Therefore, an artisan of ordinary skill would have been motivated to use the hydroxycitric acid compositions taught by US '692 and US '516 in the method taught by McCarty.

10. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Friday from 7:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SDC
December 2, 1999



FRANCISCO PRATS
PRIMARY EXAMINER